Technology for the Human

EVOLUTION™

Blood Glucose Monitoring System

Operation Manual

Auto Coding

3 sec

0.3μL

infopia Co.,Ltd.
www.infopia21.com

EVOLUTION™
Blood Glucose Monitoring System
EVOLUTION
117
mg/dL

Dear EVOLUTION™ Blood Glucose Monitoring System Owner

Thank you for choosing the EVOLUTION™ Blood Glucose Monitoring System. This booklet has important information you must know about the EVOLUTION™ Blood Glucose Monitoring System. Please read it carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. As a result EVOLUTION™ was developed to provide you with a fast and accurate reading with a convenient and simple process. Our goal at EVOLUTION™ is to provide the best quality healthcare products coupled with superior customer service. Always consult with your healthcare professional before making any changes to your diabetes management. The EVOLUTION™ Blood Glucose Monitoring System is for in vitro diagnostic use only.

Important information

The EVOLUTION™ Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use only). It should be used only for testing blood glucose and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes.

Consult your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer.

Please pay close attention when handling blood. Improper procedures may cause serious hazards to your health.

The EVOLUTION™ Blood Glucose Monitoring System contains small parts. Please keep your monitoring system out of reach of children.

Test Principle

The enzyme glucose oxidase on the blood glucose test strip reads specifically with the blood glucse. The current generated is converted and displayed as blood glucose value.
The EVOLUTION™ Blood Glucose Monitoring System is plasma-calibrated to allow easy comparison of results with laboratory methods.

Blood glucose meter which is calibrated against a whole blood method may have different results in comparison to EVOLUTION™.
The laboratory system used for calibration of the EVOLUTION™ Blood Glucose Monitoring System is YSI 2300 STAT plus which is equipped with a glucuse oxidase system.

Note

< Maintaining the EVOLUTION™ blood glucose test meter >

1. Do not assemble or disassemble the blood glucose test meter.
2. It will have to keep in the place where the water does not reach.
3. Avoid getting dirt and moisture.
4. It does not have to keep in storage place of the chemical chemicals or the place where gas etc occurs.
5. Keep out of direct sunlight.

CAUTION

1. If you do not check the code number, pull the blood glucose test strip out, conduct procedures from beginning.
2. If the code of the blood glucose test meter and of the blood glucose test strip vial does not match, you must set the code number.
3. If the code on the LCD window and on the blood glucose test vial does not match, follow the coding procedure for accurate results.

Contents

1. Learning the System
   - Intended use of Blood Glucose Test Meter 7
   - **EVOLUTION™** Blood Glucose Monitoring System Kit Contents 8
   - **EVOLUTION™** Blood Glucose Test Meter 9
   - **EVOLUTION™** Blood Glucose Test Meter Display 10
   - **EVOLUTION™** Blood Glucose Test Strip Information 11-12

2. Before Testing
   - Setting the blood glucose test meter 13-14
   - Auto-Coding Function 15
   - Performing a Glucose control solution test 16-17

3. Testing Your Blood Glucose
   - Testing Your Blood-Preparation 18
   - Collecting a Drop of Blood 19
   - Testing Procedure 20-22
   - Testing Your Blood - Case of Setting user Option and ID 23
   - Blood Glucose Test Strip Ejector Funtion 24

4. Reviewing Your Results 25-26
5. Deleting Test Results 27
6. Alternate Site Testing 28
7. Performing a Blood Test using and Alternate Site 29-30
8. **EVOLUTION™** Blood Glucose Test Meter Software 31
9. Taking Care of Your Blood Glucose Test Meter
   - Cleaning Your Blood Glucose Test Meter and Maintenance 32
   - Replacing the Batteries 33
10. Troubleshooting 34-36
11. Specifications 37
12. Conversion table mmol/L ◄► mg/dL 38
13. Warranty 39
14. Symbol reference 40

Intended use of EVOLUTION™ Blood Glucose Test Meter

The EVOLUTION™ Blood Glucose Monitoring System is intended for in vitro diagnostic use only. EVOLUTION™ Blood Glucose Monitoring System is for self-testing.
It should not be used for the diagnosis of diabetes or for the testing of new-borns.
The EVOLUTION™ was designed to test a blood glucose (sugar) level and can be used with a capillary whole blood sample.
Do not use the EVOLUTION™ Blood Glucose Monitoring System for any other than for blood glucose testing.

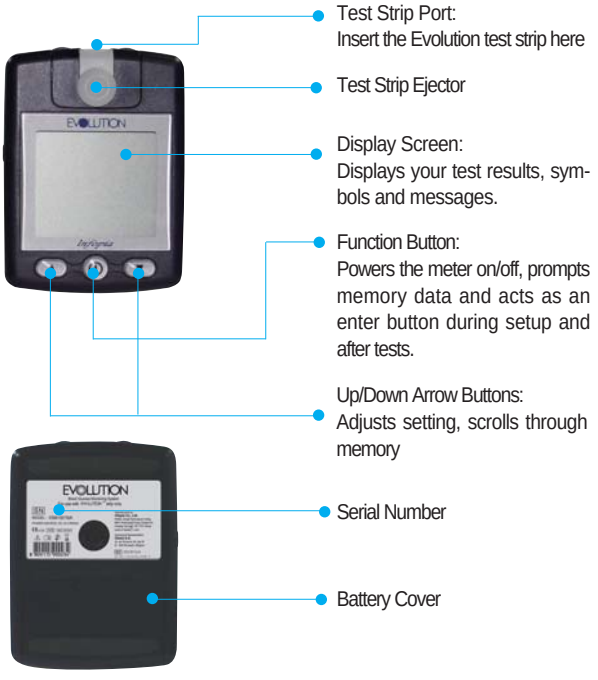
CAUTION : Before using any product, please read all instructions. Consult your physician or diabetic healthcare professional about daily management of your diabetes and proper use of the glucometer.If you have any questions about the EVOLUTION™ product, please contact your local represen tative.

EVOLUTION™ Blood Glucose Monitoring System
KIT Contents

1. EVOLUTION™ Blood Glucose Test Meter
2. EVOLUTION™ Blood Glucose Test Strips
3. Lancing Device
4. Lancets
5. Operatrion Manual
6. Warranty Registration Card
7. Patient Logbook
8. Carrying Case
9. Two 3V Li-CR2032 Batteries

Your EVOLUTION™ Blood Glucose Monitoring System has been sealed and it should contain all of the parts shown above. Please return the system to place of purchase or contact your nearest EVOLUTION™ representative if the container seals are broken or parts are missing.

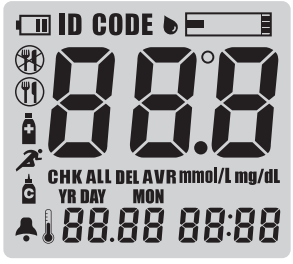
EVOLUTION™ Blood Glucose Test Meter


Test Strip Port:
Insert the Evolution test strip here
Test Strip Ejector
Display Screen:
Displays your test results, symbols and messages.
Function Button:
Powers the meter on/off, prompts memory data and acts as an enter button during setup and after tests.
Up/Down Arrow Buttons:
Adjusts setting, scrolls through memory
EVOLUTION
Serial Number
Battery Cover

CAUTION

1. Do not use EVOLUTION™ blood glucose test meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
2. Do not use EVOLUTION™ blood glucose test meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the blood glucose test meter.

EVOLUTION™ Blood Glucose Test Meter Display



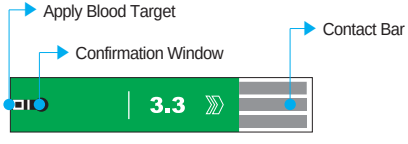
- Low Battery Warning Symbol
- ID — User ID Symbol
- CODE — Strip Code Symbol
- Blood drop symbol for test
- Alarm Symbol
- Before Having a Meal
- After Having a Meal
- After Sports Activity
- After Taking Medication
- YR DAY MON 88.88 — Temperature / Date
- 88:88 — Time / Test Result Amount
- mmol/L mg/dL — Test Result Unit Symbol
- Control Solution Symbol
- AVR — Average Test Result System
- DEL — Delete results

EVOLUTION™ Blood Glucose Test Strip Information

Storage and Handling Caution

1. Keep out of direct sunlight.
2. Store the EVOLUTION™ Blood Glucose Test Strip vials in a cool, dry place between 2-30°C(36-86°F). Do not freeze.
3. Make a notation of the discard date on the vial label when you first open it. Discard remaining EVOLUTION™ blood glucose test strips 3 months after first opening the vial.
4. Close the vial cap tightly immediately after removing a EVOLUTION™ blood glucose test strip.
5. Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
6. Avoid getting dirt, food or water on the blood glucose test strip. Do not bend, cut, or alter the EVOLUTION™ blood glucose test strip.
7. EVOLUTION™ blood glucose test strips are for single use only.
8. Keep the blood glucose test strip vial away from children.
9. Please refer to the user's manual for EVOLUTION™ blood glucose test strip for additional information.
10. Discard the used blood glucose test strip carefully, to prevent any infection.

Use only EVOLUTION™ brand blood glucose test strip with your EVOLUTION™ blood glucose test meter.



EVOLUTION™ Blood Glucose Test Strip Information

Limitations of System :
EVOLUTION™ blood glucose test strips provide accurate results when the following constraints are observed:

- Use only the EVOLUTION™ blood glucose test strips with the EVOLUTION™ blood glucose test meter.
- Use fresh capillary whole blood only. Do not use plasma or serum.
- Do not use neonate samples.
- The blood glucose test strips are for single use only. Do not reuse.
- Dehydration may lower test results. If you are severely dehydrated, contact you physician immediately.
- Inaccurate results may occur when in shock, hypotensive individuals, hyperglycemic, or hyperosmolar state, with or without ketosis.
- EVOLUTION™ blood glucose test strips may be used at altitude up to 10,000 feet without an effect on test results.

Physicians - Please note the following interferences that may affect test results :

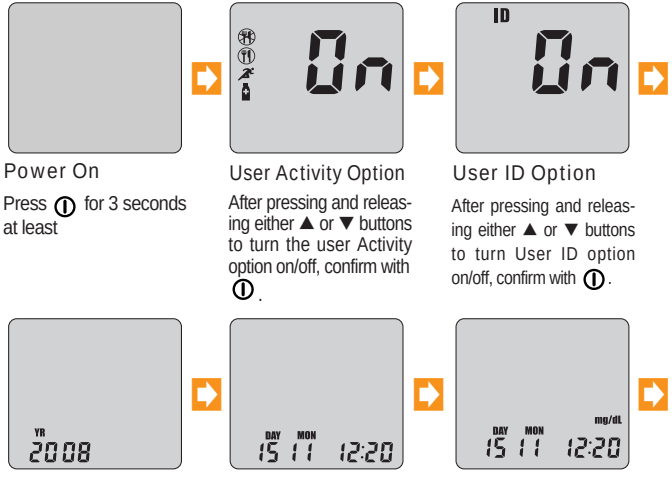
- EVOLUTION™ test strip results can be used with hematocrit levels in the range of 20% to 60%. If the hematocrit range is out of the range(20%~60%), then the test results may be lower or higher than actual value. If you do not know your hematocrit level, consult your healthcare professionals.
- Interferences: Acetaminophen, uric acid, ascorbic acid(vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results. Glucose values, however, in specimens beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

Performance Characteristics :
The performance of EVOLUTION™ blood glucose test strips has been evaluated in laboratory and in clinical tests.(please refer to strip manual for more details)

***Measurement Range*:** The measurement range of the Blood Glucose Monitoring System is 10 to 600 mg/dL (0.6-33.3 mmol/L).

Setting Your Blood Glucose Test Meter

The EVOLUTION™ Blood Glucose Test Meter has a variety of excellent functional modes; beep sound to alert when function is set, date, time, five daily alarms, unique user ID, ability to designate activities related to the test result, and the ability to designate three unique data averages.



Power On

Press ⏻ for 3 seconds at least

User Activity Option

After pressing and releasing either ▲ or ▼ buttons to turn the user Activity option on/off, confirm with ⏻.

User ID Option

After pressing and releasing either ▲ or ▼ buttons to turn User ID option on/off, confirm with ⏻.

Year

After pressing and releasing either ▲ or ▼ buttons to set the year (from 2007 to 2099), confirm with ⏻.

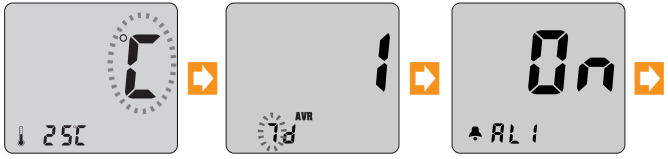
Date / Time

After pressing and releasing either ▲ or ▼ buttons to set the date and time, confirm each with ⏻.

Test Unit

Press and release either ▲ or ▼ buttons to set the test unit (mg/dL or mmol/L), confirm with ⏻.

Setting Your Blood Glucose Test Meter



Temperature unit

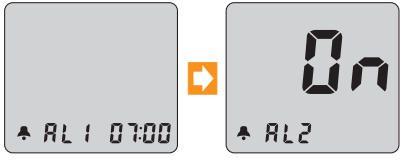
Press and release either ▲ or ▼ buttons to set ℉ or ℃. Enter ⏻ button.

Number of days for average

After pressing and releasing either ▲ or ▼ buttons to set the number of days for average calculation (3 different possible), confirm with ⏻.

Alarm on/off

After pressing and releasing either ▲ or ▼ buttons to turn the alarm on/off, confirm with ⏻



Alarm time

After pressing and releasing either ▲ or ▼ buttons to set the alarm hour and minute, confirm with ⏻.

Alarm

After programming the number of desired alarms (5 alarms possible), confirm with ⏻.

CAUTION

1. **VERY IMPORTANT: Correct test unit.
   Your ***Evolution***™ blood glucose test meter is pre-set to mg/dL as test unit. A wrong test unit will lead to wrong test result display! Please consult your healthcare professional if you're not sure which test unit to use. Stored test results are displayed correctly after re-setting the test unit. See also conversion table on page 38.
2. Without setting the date properly, the average glucose level and the results in memory will not show proper values. It is recommended to set the meter before use and when new batteries are installed.
3. Yon can't test your blood glucose while in the setting mode.
4. To turn the meter off during setup, press ⏻ for at least 3 seconds

Auto-Coding Function

1. EVOLUTION™ has automatic code recognition function.

2. It recognizes automatically the code number. This is a very convenient function preventing the inconvenience of setting the code number on the blood glucose test meter every time.

CAUTION

1. Do not bend the blood glucose test strip to prevent the Automatic code recognition failure.
2. If the code recognition label is damaged, the code recognition may fail. Please check the code number on the LCD display window with the code number on the blood glucose test strip vial.

Performing a Glucose Control Solution Test

The glucose control solution should be used when there is suspicion that the blood glucose test meter or the blood glucose test strips are not working properly. For example: if strips have been exposed to extreme conditions or if you drop the blood glucose test meter.

Check the expiration date before performing a glucose control solution test.
Do not used if expired. Once opened, solution expires after 3 months.

The Glucose control solution should be used

- Whenever you suspect the blood glucose test meter or blood glucose test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the blood glucose test meter.
- For quality control in the point of care usage.
- For teaching or learning the system.

1. Shake the glucose control solution before use.
2. Discard the 1st drop of glucose control solution, this will eliminate any residue.
3. Place a drop of glucose control solution on a clean dry surface (ex. The lid of the blood glucose test strip vial).
4. Insert a blood glucose test strip into the port and press the up arrow. A glucose control solution vial will appear on the bottom left hand side of the screen, above the date and time. This will allow you to differentiate between a glucose control solution test and an actual blood test for future reference.

5. Dip the blood glucose test strip into the glucose control solution.
6. Results appear in 3 seconds.
7. Compare the result to the range printed on the blood glucose test strip vial, the results should fall within that range.
8. If your glucose control solution falls out of range, do not perform a glucose test, please contact your local representative.

Performing a Glucose Control Solution Test

Note: - **EVOLUTION™** glucose control solution is sold separately.
- It is recommended that glucose control solution is stored at room temperature 20~25℃ (68～77℉) before testing.

For example
If you use a normal glucose control solution, you must use the normal range printed on the side of the blood glucose test strip vial.

- Results that fall outside the expected range may indicate:
  - Test not performed at room temperature.
  - An error in the way you are doing the test.
  - Expired or contaminated glucose control solution.
  - A problem with the blood glucose test meter.
  - Glucose control solution that is too warm or cold.
  - Failure to discard the first drop of glucose control solution and to wipe the bottle tip clean.
  - Failure to shake the glucose control solution adequately.

CAUTION
- If your glucose control solution falls out of range, do not perform a glucose test, please contact your local representative.
- The Glucose Control Solution range is not the recommended range for your blood glucose level.

Testing Your Blood - Preparation

Before testing, be sure to read this section and blood glucose test strip package insert found in the blood glucose test strip box carefully, Make sure you have all the necessary items to begin testing:

- EVOLUTION™ blood glucose test meter
- EVOLUTION™ blood glucose test strip
- Lancing Device
- Sterile Lancets

CAUTION

To reduce the chance of infection.

- The Lancing Device and sterile lancets should NOT be shared with others.
- Always use a new, sterile lancet and new blood glucose test strip.
- Lancets are for single use only. DO not reuse.
- Avoid getting hand lotion, oils, dirt, or debris in or on the Lancets and the Lancing Device.
- Dry your hands completely before testing.

Practice using the lancing device and become accustomed with its use.
Wash your hands with warm, clean water and soap. Dry your hands completely before testing.

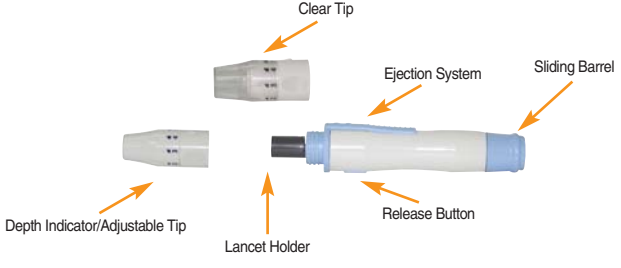
Collecting a Drop of Blood

The lancing device is a convenient medical tool for collecting capillary blood samples for glucose monitoring or other tests which require one or two drops of blood. As a more advanced lancing device, it provides ultimate safety and comfort for obtaining blood samples. An adjustable tip offers 5 levels of skin penetration for individual user's comfort and a lancet ejector enables the safe disposal of the used lancet. As an added bonus, the also comes with a transparent tip for AST (Alternative Site Testing).

PRECAUTIONS

- Never use a lancet that has been used by someone else. This could lead to contamination.
- If the lancing device is to be used by another person, the unit must be properly disinfected and a new tip and lancet must be used.
- Do not leave the lancet in the device after use.
- A new lancet must only be placed into the lancing device directly before testing.
- This device has many small parts and could be a choking hazard for children if swallowed.
- In the case of hospital use, hospitals need to consult their own infection control protocols in order to avoid any contamination.
- Always dispose of the used lancet in a biohazard garbage container.

COMPONENTS



Collecting a Drop of Blood

1. Unscrew the tip of the lancing device by turning it counter-clockwise while holding the base firmly.

2. With two fingers, pull out the lancet carrier and hold it in place.

3. While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier.

4. Twist the cap of the lancet off.

5. Put the tip of the lancing device back on and turn it clockwise.

6. Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancing device.

7. Place the lancing device in place. Hold the firmly against the side of the finger, with the cap resting on the finger. (The harder it is pressed the deeper the puncture.) Press the release button to take a sample.

8. Unscrew the tip of the lancing device by turning it counter-clockwise.

9. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.

Collecting a Drop of Blood

RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are BD-Ultra Fine, Cleanlet Fine, E-Z Ject, G-P Lite, Microlet, Monolet, One Touch, Soft Touch, Therasense, Ultra TLC and Unilet GP.
Note: Some less known lancets may not work properly with the due to their dimensions. Please, contact your supplier to make sure you are using proper lancets.

USING THE CLEAR TIP (AST)

1. Place the on the skin in the chosen area, press and hold the continuously for a few seconds, then push the release button to take a sample.
2. Watch through the clear tip until a sufficient blood sample is taken. If there is not enough blood, gently massage the area until a sufficient sample has been collected.

STORAGE

Products must be stored at room temperature protected from sunlight or moisture.

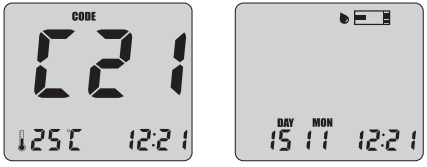
CLEANING AND DISINFECTION

Clean and wipe the outside of the lancing device a minimum of once a week with a soft cloth, dampened with mild soap and water. Wash the adjustable tip and the clear tip once a week with mild soap. DO NOT immerse the in liquid.

WARRANTY

Lancing device has a 2-year warranty from the date of purchase. A malfunctioning device should be returned to the following address:

Manufacturer :
GMMC
Room No. 1112, Ace Tower 9th Bldg., 345-30, Kasan-Dong, Kumchon-Ku, Seoul, South Korea
Tel : +82 2 2104 0470
Fax : +82 2 2104 0472
EU Authorized Representative :
GMMC, S.L.
C/Vinalopo' 4 - 1° - Pta 4 Valencia, Spain
Tel : +34 963 691 484
Fax: +34 961 125 949



Step 1

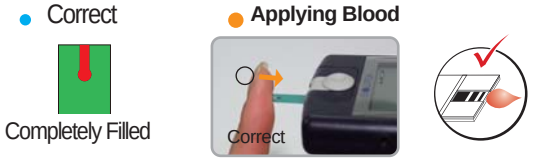
- Firmly insert the blood glucose test strip into the blood glucose test meter port with the "**3.3**" facing towards you.
- The blood glucose test meter automatically turns on displaying the code, ambient temperature and the date and time.
- The EVOLUTION™ will automatically recognize the blood glucose test strip code number and adjust the blood glucose test meter accordingly.
- A blinking blood glucose test strip will appear at the top of the screen indicating the blood glucose test meter is ready for testing.

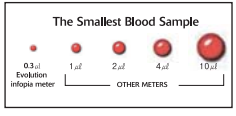
Note : Inserting the test strip in the wrong direction will turn the meter on, but you will be unable to test.

CAUTION

1. If the code is not displayed after for a while, pull the blood glucose test strip out of the port, and re-start the procedure from the beginning.
2. If the code on the LCD display window and on the test vial does not match, try another new blood glucose test strip. If the mismatch persists, please contact your local representative for help.
3. If the meter does not power on, pull the blood glucose test strip out of the port, and re-insert the blood glucose test strip.
4. Avoid testing under direct sunlight, for a more accurate test result.
5. If you apply your blood sample too early, ERROR5 message will appear on LCD (refer to p35).

• For a more accurate test result avoid testing under direct sunlight.





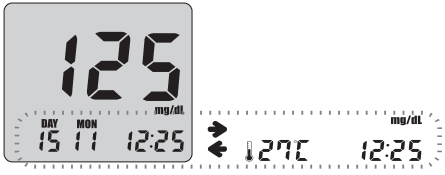
- **Evolution**™ blood glucose test meter only requires 0.3㎕ sample volume.

Step 2

- Place the top edge of the blood glucose test strip to the area you prepared for testing.
- The blood will automatically be "drawn" into the blood glucose test strip channel.
- When the chamber has enough blood, your blood glucose test meter will automatically count down.

CAUTION

1. If the countdown does not start, do not add more blood to the blood glucose test strip! Discard the blood glucose test strip an restart testing.
2. If you do not conduct the test within 3 minutes, the blood glucose test meter will automatically power off to save battery life. In this case the test procedure should start again from the beginning.



Step 3

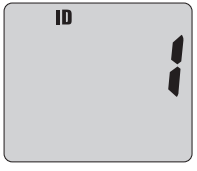
- After beeping sound, the test will begin automatically and your results will appear in 3 seconds. It should begin counting down from 3 to 1 second on the LCD window. The LCD window will display the result of your blood glucose level, including temperature and time.
- Record the result value in your EVOLUTION™ logbook. When you pull out the blood glucose test strip, the meter turns off automatically.

CAUTION

1. If the test result is out of the test range, the Hi/Lo message will be shown on the LCD window. (refer to p35)
2. Safely discard used blood glucose test strips and lancets.

Step 4-1

- If you selected to use the User Activity option during set up, press ▲ and ▼ button to select the activity that correlates with your result (refer to p10), then press ⓘ .
- If you do not select to use user activity option during set up, press ⓘ to continue to step 4-2.



Step 4-2

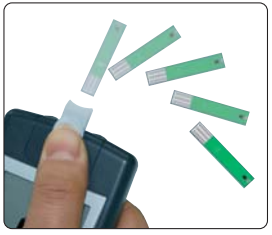
- If you selected to use the User ID option during setup, press ▲ and ▼ button to select the correct User ID, then press ⓘ .

CAUTION

1. If you did not activate the User Activity option and/or the User ID option, Step 4-1 and/or Step 4-2 procedures are not conducted.
2. Although User Activity option and/or User ID option are activated, if you pull the blood glucose test strip out right after the test, you can not move onto step 4, The test result is stored, not under a specific User ID and only displayed after deactivating the User Id option.
3. Please refer to page 13, if you want to set the User Activity option and User ID option.

Test Strip Ejector Function

Press and Push forward



Eject your blood glucose test strip

1. Once the test is complete, slide the ejector button forward to remove the blood glucose test strip from the blood glucose test meter.
2. Discard the used blood glucose test strip and lancet accordingly.

CAUTION

1. If you push the ejector button forward too much, it may be part of the failure.
2. Do not give strong impact to blood glucose test meter.

Reviewing Your Result

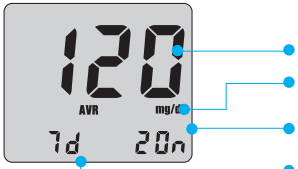
The EVOLUTION™ blood glucose test meter stores up to 365 test results in its built-in memory, along with the average sugar level for the number of days which you had preset the blood glucose test meter to calculate. These values can be recalled in the LCD display at any time.

- Press and release ⓘ button. The most resent result first if user ID feature has been elected during setting the blood glucose test meter.
- Check your previous result by pressing the arrow ▼ button.
- Check your average data by pressing the arrow ▲ button.

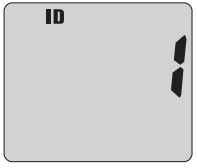
The third latest | The second latest | The latest

7day average from the test date | 14 day average from the test date | 21day average from the test date

Reviewing Your Result

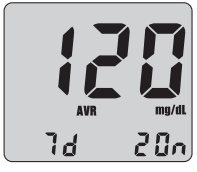


- Average test result
- Test Unit
- Test result amount
- Average test result days



- Pressing the ⓘ button once and the User ID option will appear in the LCD screen.

- After entering the user ID mode, use ▲ and ▼ button to scroll and choose the correct user ID, then press the ⓘ button.



- If you choose the User ID to check the stored results, only the results of the selected user are displayed.

Deleting Test Results

Deleting individual test result

To delete any individual test result in the memory press ▲ or ▼ button for 3 seconds, while the test result to delete is displayed. is **DEL** blinking. After the second beep sound the test result is deleted.

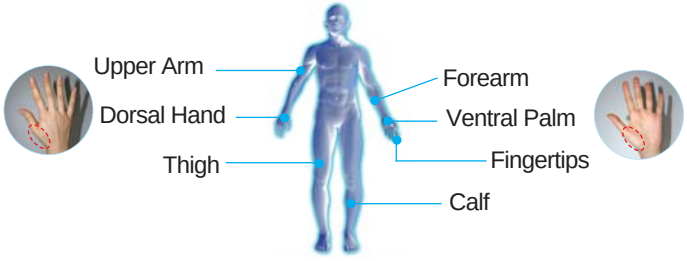
Deleting all test results

To delete all test results press ▲ and ▼ button at the same time for 3 seconds, while any test result is displayed. **ALL DEL** is blinking. After the third beep sound all test results are deleted.

Caution

- Only selected Individual test results are deleted when you recalled test results in the user ID condition
- The deleted test results can't be recovered. Please be careful in deleting the test results.

Alternate Site Testing



Important Information About Using Alternative Sites Testing :

- Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternate sites may differ significantly from fingertip samples
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, as insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood glucose) level sooner than a test with a alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptom to indicate as insulin reaction), as forearm testing may fail to detect hypoglycemia.

Important :
We recommend that you test on your fingertips if you are testing for hypoglycemia (low blood glucose) or if you are suffering from hypoglycemia unawareness.

Performing a Blood Test Using and Alternate Site

Performing a Blood Test Using an Alternate Site To ensure accurate results when lancing your forearm, upper arm, hand, thigh, or calf, wash the test site with soap and water.

Make sure there is no cream or lotion on the test site.Thoroughly dry your hands and test site.

CAUTION

- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hand and test site with soap and water.
- To receive accurate test results, at least 0.3㎕ minimum sample volume is required.

Performing a Blood Test Using and Alternate Site

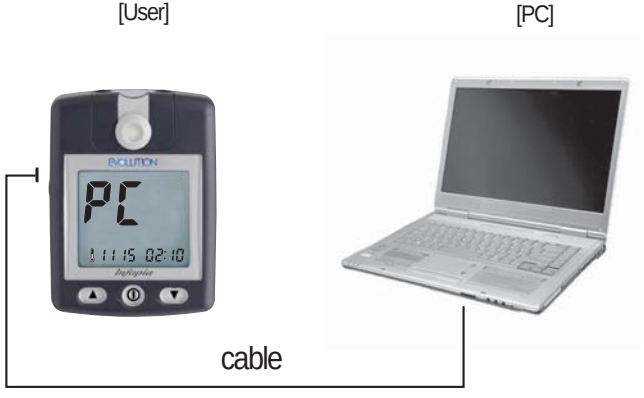
To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm.

Lance the test site with the lancing device:

1. Hold the clear cap down against the top of your test site. Press the release button. Do not lift up.
2. Continue to hold the lancing device and gradually increase pressure for several seconds.
3. While holding the lancing device on your test site, look through the clear cap; until a drop of blood appears approximate • size
4. Lift the lancing device straight up; be careful not to smear the blood on your testing site.
5. Place the edge of the blood glucose test strip to the drop of blood.
6. The blood will automatically draw into the channel of the blood glucose test strip.

EVOLUTION™ Blood Glucose Test Meter Software

You can transfer test results from the EVOLUTION™ blood glucose test meter to a computer.
You can download the software from our web site.
(http://www.infopia21.com)
You can purchase the computer communication cable separately from a local representative.



Cleaning Your Meter and Maintenance

Meter

Your meter does not require special maintenance or cleaning. avoid getting dirt, dust, blood, glucose control solution, or liquids on the blood glucose test meter, the test port, or data port. Your blood glucose test meter operation temperature is 10℃~40℃(50℉～104℉).

It is recommended that you store the meter in its carrying case after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outside of the blood glucose test meter. Your **EVOLUTION**™ blood glucose test meter is a precision instrument. Please handle it with care.

Lancet Device:

Clean the lancet device and caps with soap and tepid water. To disinfect the lancet device, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the lancet device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution. Do not soak the lancet device in liquid. Rinse the lance device and cap with water and dry thoroughly.

- For detailed instructions concerning **EVOLUTION**™ blood glucose test strips, refer to the test strip package insert found in the blood glucose test strip box.
- Please store the **EVOLUTION**™ blood glucose monitoring system in a cool, dry area, out of reach of children. Do not freeze. For a more accurate test result avoid testing under direct sunlight.
- Do not soak the blood glucose test meter or blood glucose test strips in water or liquid.
- Do not subject the blood glucose test meter or blood glucose test strips to excessive heat.
- Use your blood glucose test meter according to the instructions in the manual.
- If you need to purchase the lancing device, lancets or blood glucose test strips, contact your local representative.
- Discard the used Lancets carefully, to prevent any infection.

Replacing the Batteries

The low battery icon will appear in the upper left corner of the LCD screen to alert you when the battery power is running low, indicating a new battery is needed.

Your **EVOLUTION**™ blood glucose test meter uses only two 3V Lithium batteries (CR2032), which are included. When replacing the batteries, only CR2032 or equivalent lithium battery should be used.

After changing the batteries, please be sure to recheck your meter settings.

<Follow-up Action>

1. Check your meter with the glucose control solution (p16-17)
2. Perform your test again (p20 - 22)
3. If you are experiencing symptoms that are not consistent with your blood glucose test results, call your healthcare professional.

CAUTION

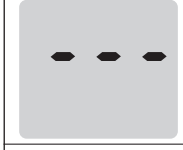
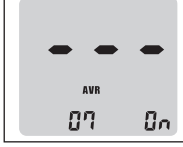
Remove both batteries from the battery compartment and dispoes of them according your institution's guidelines.

The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or Infopia USA customer support if the problem persists.

Message	Problem	Action Required
	Problem with the blood glucose test meter	Place the battery again, and set the blood glucose test meter. If the problem persists, please contact your authorized representative or customer support
	Caused by either used or wet blood glucose test strip	Please insert a new blood glucose test strip and perform your test again
	Blood glucose test strip is damaged	Please insert a new blood glucose test strip and perform your test again
	User applied the blood sample before the LCD display was blinking	Please wait for the LCD to display icon blinking before applying your blood sample

Message	Problem	Action Required
	Problem with the Auto-coding label	Please insert a new blood glucose test strip and perform your test again. If the problem persists, pleas contact your authorized representative or customer support.
	The ambient temperature is too low	Place the blood glucose test meter within the operating temperature range for 10 minutes or more and retest.
	The ambient temperature is too high	Place the blood glucose test meter within the operating temperature range for 10 minutes or more and retest.
	The test result is lower than 10mg/dl	Check the accuracy of your blood glucose test strip by performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Lo" persists, consult your doctor immediately.
	The test result is higher than 600mg/dL	Check the accuracy of your blood glucose test strip by performing a glucose control solution test. If the test results in a normal reading, re-test your blood sample two or three times. If "Hi" persists, consult your doctor immediately.

Troubleshooting

Message	Problem	Action Required
The blood glucose test meter does not power on	Battery is dead or there is a problem with the blood glucose test meter	Change the battery and if the problem persist, contact your local representative
Test does not start after applying blood sample	Poor blood sample	Please insert a new blood glucose test strip and perform your test again
The result is inconsistent	There may be a problem with the blood glucose test strip	Please insert a new blood glucose test strip and perform your test again
	No readings in memory to display	
	No enough readings in memory to display designated averages	

Specifications

Sample type	Capillary whole blood
Sample volume	0.3ul
Test Range	10~600 mg/dL
Reading time	3 seconds
Calibration	Plasma - Equivalent
Altitude	≤3048m (10,000 feet)
Operating Temperature	10-40℃(50-104°F)
Operating Humidity	10-90%
Strip storage temperature	2-30℃ (36-86°F)
Display Type	LCD
Dimension	76 X 56 X 18 (mm)
Weight	45g (Including Battery)
Power rating	3 V Li Battery (CR2032) X 2
Battery Life	5,000 running tests
PC communications port	Communication available

Conversion table mmol/L ↔ mg/dL

mmol/L	0.55	1.0	1.5	2.0	2.2	2.5	2.8	3.0
mg/dL	10	18	27	36	40	45	50	54
mmol/L	6.7	7.0	7.2	7.5	7.8	8.0	8.3	8.9
mg/dL	120	126	130	135	140	145	150	160
mmol/L	14.4	15.0	16.0	16.6	17.0	18.0	19.0	20.0
mg/dL	260	270	288	300	306	325	342	360
mmol/L	3.3	3.9	4.0	4.4	4.7	5.0	5.5	6.0	6.1
mg/dL	60	70	72	80	85	90	100	108	110
mmol/L	9.0	9.4	10.0	10.5	11.0	11.1	12.0	12.5	13.9
mg/dL	162	170	180	190	196	200	216	225	250
mmol/L	20.8	22.2	23.0	24.0	25.0	26.4	27.7	30.0	33.3
mg/dL	375	400	414	432	450	475	500	540	600

Warranty

Three - Year Warranty

If, at any time during the first three years after purchasem the blood glucose test meter does not work for any reason with the exception of obvious abuse, misuse, or disastrous damage, Infopia Co.,Ltd. will replace your EVOLUTION™ blood glucose test meter or equivalence free of charge.

The Warranty Policy of Infopia Co.,Ltd. only applies to the original purchaser of the Meter and will not include the batteries supplied with the blood glucose test meter set.

Please fill in the warranty card attached to the set.
Mail or fax it back to us.

The EVOLUTION™ blood glucose test meter has a full three-year warranty from the original date of your purchase. For your convenience, please include your date and place of purchase.

Symbol Reference

Symbol	Description
	Consult Instructions for use
	Used By
CE 0123	This prodect fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Caution, consult accompanying documents
IVD	For In Vitro Diagnostic Use
LOT	Batch code
REF	Catalogue Number
	Temperature limitation
	Do not re-use
SN	Serial number
	Date of Manufacture
	Manufacturer
	Keep away from sunlight
SELF-TESTING	For Self-testing
	Separate collection for waste electrical and electorinic equipment

infopia Co., Ltd.

infopia Co., Ltd.
#1603, Dongil Technotown A bldg.
889-3, Kwanyang2-Dong,
Dongan-Gu, Anyang,
Kyunggi, 431-716,
Korea
CE 0123

EC REP **Obelis S.A**
Bd. General Wahis 53,
1030 Brussels, Belgium
Tel: +(32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail : mail@obelis.net

Lancing Device : **GMMC**
Room No. 1112, Ace Tower 9th Bldg.,
345-30, Kasan-Dong,
Kumchon-Ku,
Seoul, South Korea
CE

Lancet : **SAE HAN Medical Corp.**
1155-1, Pubgot-Dong, Ilsanseo-Gu,
Goyang-City,
Gyeonggi-Do,
Korea
CE 0434

REF INFM16A